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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,140	07/19/2004	Jung Joon Lee	04-417	9176

34704 7590 03/02/2007

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EXAMINER	
MCCORMICK EWOLDT, SUSAN BETH	
ART UNIT	**PAPER NUMBER**
1661	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,140	LEE ET AL.	
	Examiner	Art Unit	
	S. B. McCormick-Ewoldt	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment of January 19, 2007 is hereby acknowledged and entered.

Claims Pending

Claims 1-10 are pending.

Claim Rejections - 35 USC § 112

Applicant's arguments, see pages 4-5 of the response, filed January 19, 2007, with respect to claim 1 have been fully considered and are persuasive. The rejection of claim 1 has been withdrawn.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Palladino *et al.* (6,365,768) for reasons set forth in the previous Office action which are restated below. Applicant's arguments filed January 19, 2007 have been fully considered but they are not persuasive.

Applicant's claims are drawn to product-by-process claims. The product is an extract from *Acanthopanax koreanum* stem or root. Regarding product-by-process claims, note that MPEP § 2113 states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate...A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972); In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)."

Palladino *et al.* (6,365,768) teach using an extract of *Acanthopanax koreanum* to inhibit Tumor Necrosis Factor-α (i.e. TNF-α), which can be attributed to viral infections such as hepatitis viruses and cirrhosis (column 2, lines 4-5; column 14, lines 29-33; column 22, lines 19-37).

The reference does not specifically teach that the product is extracted using the method claimed by Applicant in claim 1 or that the extract contains all of the characteristics claimed in claims 2, 3 and 4. However, the reference product reasonably appears to be the same product as claimed because the reference product is extracted from the same source as claimed and has the same TNF-α (i.e. Tumor Necrosis Factor-α inhibitory activity and viral infection (i.e. hepatitis)) is claimed.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extract as evidence by their shared TNF-α (i.e. Tumor Necrosis Factor- α inhibitory activity and viral infection (i.e. hepatitis)).

Applicant's arguments concerning the above art rejection have been fully considered but are not deemed to be persuasive.

Applicant argues that Palladino extract of *Acanthopanax koreanum* contains acanthoic acid while the experiments set forth by the inventor demonstrated that the water extracts from both the root and stem of *Acanthopanax koreanum* does not contain acanthoic acid. This is not found persuasive because Applicant has not fully defined the extract procedure as claimed.

Therefore, the rejection is deemed proper and is maintained.

Claims 1-10 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pyun *et al.* (5,900,434). Applicant's arguments filed January 19, 2007 have been fully considered but they are not persuasive.

Applicant's claims are drawn to product-by-process claims. The product is an extract from *Acanthopanax koreanum* stem or root. Regarding product-by-process claims, note that MPEP § 2113 states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate...A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972); In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)."

Pyun *et al.* (5,900,434) teach using an extract of *Acanthopanax koreanum* to inhibit Tumor Necrosis Factor-α (i.e. TNF-α) which can be attributed to hepatocirrhosis (column 3, lines 41-55; column 4, lines 4-11).

The reference does not specifically teach that the product is extracted using the method claimed by Applicant in claim 1 or that the extract contains all of the characteristics claimed in claims 2, 3 and 4. However, the reference product reasonably appears to be the same product as claimed because the reference product is extracted from the same source as claimed and has the same TNF-α (i.e. Tumor Necrosis Factor-α inhibitory activity and viral infection (i.e. hepatitis)) is claimed.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extract as evidence by their shared TNF-α (i.e. Tumor Necrosis Factor- α inhibitory activity and viral infection (i.e. hepatitis)).

Applicant's arguments concerning the above art rejection have been fully considered but are not deemed to be persuasive.

Applicant argues that the Pyun extract of *Acanthopanax koreanum* contains acanthoic acid while the experiments set forth by the inventor demonstrated that the water extracts from

both the root and stem of *Acanthopanax koreanum* does not contain acanthoic acid. This is not found persuasive because Applicant has not fully defined the extract procedure as claimed.

Therefore, the rejection is deemed proper and is maintained.

Declaration

The declaration has been considered.

However, the declaration raises questions that the Examiner could not find support for in the specification, as filed, such as the water extract taken from either the root or stem of *Acanthopanax koreanum* as recited in claim 1 does not contain acanthoic acid. The specification does not disclose that the water extract of *Acanthopanax koreanum* does not contain acanthoic acid.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Summary

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

CHRISTOPHER R. TATE
PRIMARY EXAMINER